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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,952	11/27/2001	Michael G. Walker	PB-0016 US	2398

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INCYTE CORPORATION (formerly known as Incyte
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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/996,952

Applicant(s)

WALKER ET AL.

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2, 3, 9, 10, 11, drawn to a combination comprising a nucleic acid selected from SEQ ID NOs: 4, 6, and 7, vectors and host cells comprising said nucleic acid, classified in class 435, subclass 183.
- II. Claim 4, drawn to a method of using a cDNA to screen for a plurality of molecules to identify at least one ligand, classified in class 435, subclass 6.
- III. Claims 5-8, drawn to a method of using a cDNA to detect differential expression in a sample, classified in class 435, subclass 6.
- IV. Claims 12 and 13, drawn to a purified protein, classified in class 435, subclass 183.
- V. Claim 14, drawn to a method of using a protein to screen for a plurality of molecules to identify at least one ligand, classified in class 435, subclass 252.3.
- VI. Claim 15, drawn a method of using a protein to prepare an antibody, classified in class 435, subclass 252.32.
- VII. Claims 16 and 17, drawn to isolated antibody, classified in class 530, subclass 387.1.

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VIII. Claims 18 and 19, drawn to a method for using an antibody to detect expression in a sample, classified in class 435 subclass 7.1.

IX. Claim 20, drawn to a method for using an antibody to immunopurify a protein, classified in class 435, subclass 7.1.

For each of inventions I-IX above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of inventions I-VI and one of inventions (A)-(P).

(A). SEQ ID NO: 4.

(B). SEQ ID NO: 6.

(C). SEQ ID NO: 7.

It is noted that claim 1, which has been grouped with Group I, is drawn to a combination comprising a plurality of cDNAs having the nucleic acid sequence of SEQ ID NO: 1-9 and the complements of SEQ ID NO: 1-9. Thus this claim requires that the combination **must comprise each of SEQ ID NO: 1-9** as well as the complements of SEQ ID NO: 1-9. This claim is supported by the specification on page Should applicants amend this claim such that it is drawn to a combination comprising a plurality of cDNAs **selected from the group consisting of SEQ ID NO: 1-9** and the complements of SEQ ID NO: 1-9, a further restriction will be made between SEQ ID NO: 1-9 and the complements of SEQ ID NO: 1-9.

The inventions are distinct, each from the other because of the following reasons:

Inventions (A)-(C) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, represent structurally different polynucleotides. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects.

Inventions I, IV, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotides of Groups I, the proteins of Group IV and the antibody of Groups VII each comprise a chemically unrelated structure capable of separate manufacture, use and effect. The polynucleotides of Groups I are comprised of a nucleic acid sequence and the proteins of Group IV and the antibody of Group VII are comprised of different amino acid sequences. The polynucleotides have other utility besides encoding proteins such as a hybridization probe, and the proteins can be made synthetically. Additionally, the protein can be used to perform specific biological function(s) which are independent of the function(s) of the DNA molecule. The protein has other utility such as for methods of production of antibodies against the proteins.

Inventions I and inventions II and III are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

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materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotides of Group I can be used in a materially different process such as one in which they are used to synthesize the encoded proteins.

The inventions of Groups IV and VII are unrelated to the methods of Groups II and III, as they are neither used nor made by the methods of Groups II and III.

Inventions IV and inventions V and VI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of Group IV can be used in a materially different process such as a method of indicating the expression of steroid synthesis genes.

The inventions of Groups I and VII are unrelated to the methods of Groups V or VI as they are neither used nor made by the methods of Groups V or VI.

Inventions VII and inventions VIII and IX are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of Group VII can be used in a materially different process such as a method of characterizing a protein molecule.

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The inventions of Groups I and IV are unrelated to the methods of Groups VIII or VIX as they are neither used nor made by the methods of Groups VIII or IX.

The methods of Groups II, III, V, VI, VIII and IX are independent as they comprise different steps, utilize different products and produce different results.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax

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phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', written over a horizontal line.

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rg
June 2, 2003